SUMMARY OF SAFETY AND EFFECTIVENESS
MP-1 MICRO PERIMETER

SUBMITTER INFORMATION

A.	Company Name:	Nidek Technologies Srl
B.	Company Address:	Via Regina, 88 Vigonza (Padova), Italy 35010
C.	Company Phone: Company Fax:	39 49 89 35 191 39 49 62 55 84
D.	Contact Person:	Mr. Aldo Cocchiglia Managing Director Nidek Technologies Srl
E.	Date Summary Prepared:	July 03, 2002

DEVICE IDENTIFICATION

A.	Generic Device Name:	Ophthalmic camera, AC-powered Automated Micro Perimeter, AC-powered
B.	Trade/Proprietary Name:	MP-1 MICRO PERIMETER
C.	Classification:	Class II
D.	Product Code:	HKI , HPT

DEVICE DESCRIPTION

The Nidek Technologies Srl MP-1 MICRO PERIMETER is an instrument for the diagnosis of retinal diseases. It is able to capture infrared live sequences and color images of the patient retina through CCD cameras and at the same time to project light stimuli on the retina in those retinal positions chosen by the operator.

The MP-1 MICRO PERIMETER is supplied with Xenon light and Halogen light sources suitable for performing the above described examinations.

The system includes also a suitable Insulation transformer, a 15-inch LCD S-VGA Monitor and an IBM Personal Computer, which incorporates the dedicated NAVIS software (with Windows 2000 operative system).

INTENDED USE

The MP-1 MICRO PERIMETER is intended for use as:

1) Color retinography

Color image of the fundus obtained in non-mydriatic conditions, using an IR sensible camera as a viewfinder and a visible flash for illuminating the retina at picture taking.

2) Fixation exam

This examination consists in:

- locating, in the patient's fundus, his/her fixation site (anatomical information);
- recording the positions, during a certain interval, of the point at which the patient is fixating, as a measure of fixation stability (functional information).

3) Fundus-related microperimetry

Consists in:

- projecting light stimuli on patient retina at given positions;
- recording the patient's subjective answer to each stimulus (seen/ not seen);
- associating precisely the subjective answers (functional information) with the retinal location of the stimuli (anatomical information), compensating properly for eye fundus movements during the examination;
- generating a sensitivity map of the inspected retinal region.

SUBSTANTIAL EQUIVALENCE

The Nidek Technologies Srl MP-1 MICRO PERIMETER device is of comparable type and is substantially equivalent to the following predicate device :

Predicate Device	510(K) Holder	510(k) No.	Date Cleared
NON-MYDRIATIC FUNDUS CAMERA, MODEL NM-1000	NIDEK, INC	**K014274**	04/17/2002
HUMPHREY FIELD ANALYZER	CARL ZEISS, INC.	**K954167**	11/24/1995
CONFOSCAN 2 CONFOCAL MICROSCOPE	NIDEK TECHNOLOGIES SRL	**K012416**	10/26/2001

In further support of a substantial equivalence determination, Section 10 provides a comparison chart of the MP-1 MICRO PERIMETER and the predicate devices.

TECHNOLOGICAL CHARACTERISTICS

A comparison of the technological characteristics of the MP-1 MICRO PERIMETER and the predicate devices has been performed. The results of this comparison demonstrate that the MP-1 MICRO PERIMETER device is equivalent to the marketed predicate devices.

PERFORMANCE DATA

The performance data indicate that the MP-1 MICRO PERIMETER device meets all specified requirements, and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 2 3 2002

Nidek Technologies, Srl
c/o TUV America, Inc.
Attention: Mr. Mark Job
1775 Old Highway
New Brighton, MN 55112-1891

Re: K023719
Trade Name: MP-1 MICRO PERIMETER
Classification Regulation Number: 886.1120; 886.1605
Regulatory Class: II and I
Product Code: HKI; HPT
Dated: December 9, 2002
Received: December 12, 2002

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

INDICATIONS FOR USE

510(k) Number: K023719 (To Be Assigned By FDA)

Device Trade Name: MP-1 MICRO PERIMETER

Indications For Use: The MP-1 MICRO PERIMETER is indicated for use as :

- *Color retinography*
- *Fixation examiner*
- *Fundus-related microperimetry*

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises
510(k) Number K023719

Prescription Use ✓ OROver-The-Counter Use _____

(Per 21 CFR 801.109)